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JANSSEN PHARMACEUTICALS, INC.
AND MCKESSON CORPORATION

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

SYLVESTER DUMAS; BEVERLY MATHERNE, individually, and as Executor of the Estate of ASHLEY JOSEPH MATHERNE, deceased; DONALD TINDALL; GLENDA BALLARD; RHEISSIE L. BALLARD, JR.; THOMAS MOYERS; KIMBERLY THOMPSON; and DOUGLAS THOMPSON;

Plaintiffs,

v.

JANSSEN PHARMACEUTICALS, INC.; JANSSEN RESEARCH AND DEVELOPMENT, LLC; JOHNSON & JOHNSON; JANSSEN ORTHO, LLC; MITSUBISHI TANABE PHARMA HOLDINGS AMERICA, INC.; MITSUBISHI TANABE PHARMA DEVELOPMENT AMERICA, INC.; TANABE RESEARCH LABORATORIES U.S.A., INC.; MITSUBISHI TANABE PHARMA CORP.; MCKESSON CORPORATION; and DOES 1-50;

Defendants.

Case No. 3:16-cv-00647-L-WVG

Hon. M. James Lorenz

REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS JANSSEN PHARMACEUTICALS, INC. AND MCKESSON CORPORATION'S MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT PURSUANT TO FEDERAL RULES OF CIVIL PROCEDURE 12(b)(2) AND 12(b)(6)

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I. INTRODUCTION.

Plaintiffs fail to address many of Defendants' arguments, concede other arguments, and generally misstate the law. The Court should dismiss the First Amended Complaint.

II. ARGUMENT.

A. The Court Should Dismiss All Of The Non-California Plaintiffs' Claims As Against Janssen For Lack Of Personal Jurisdiction.

As explained, Janssen is not subject to general jurisdiction. *See* Defs.' Mem. at 4–5. Plaintiffs do not disagree. *See* Pls.' Opp'n at 5 ("Plaintiffs have not addressed Defendants' general jurisdiction arguments.").

In addition, the Non-California Plaintiffs have not demonstrated that Janssen is subject to specific jurisdiction with respect to their claims. They concede that their purported injuries have no connection to Janssen's alleged California conduct. Instead, they argue—without *any* legal support—that Janssen is subject to specific jurisdiction because (1) it supposedly acted "in concert" with TRL and McKesson, and (2) a different defendant—Janssen Research and Development LLC ("JRD")—supposedly conducted clinical trial work in California. *See id.* at 5–6. Neither argument has merit.

First, a non-resident defendant is *not* subject to personal jurisdiction for alleged conduct "in concert" with a forum defendant in the absence of an actionable conspiracy claim. *See Murphy v. Am. Gen. Life Ins. Co.*, 2015 WL 4379834, at *8 (C.D. Cal. July 15, 2015) ("It has long been recognized that personal jurisdiction over a defendant . . . may be present in a forum so long as an actionable conspiracy is pled and a substantial act in furtherance of the conspiracy is performed in the forum state." (internal citations omitted)). But Plaintiffs have *not* alleged a claim for civil conspiracy. *See generally* First Am. Compl. In fact, the words "conspire" or "conspiracy" do not appear anywhere in the First Amended Complaint. *See generally id.* Thus, Janssen is not subject to personal jurisdiction based on Plaintiffs' unsupported acting-in-concert theory.

Second, JRD's purported California contacts are not imputable to Janssen.

Plaintiffs do *not* allege *any* facts that would permit the imputation of JRD's contacts to Janssen on an alter ego theory. *See generally id.*; *see also Beco Dairy Automation, Inc. v. Global Tech Sys., Inc.*, 2016 WL 783058, at *6 (E.D. Cal. Feb. 29, 2016) ("A court may only attribute a subsidiary's contacts with the forum state to its parent 'upon a showing that the subsidiary is an alter ego of its parent.'") (quoting *Ranza v. Nike, Inc.*, 793 F.3d 1059, 1065 (9th Cir. 2015)). Moreover, if the Non-California Plaintiffs' argument—*i.e.*, that JRD's purported California contacts were sufficient to confer specific jurisdiction over Janssen—were correct (and it is *not*), Janssen would be subject to jurisdiction in California with respect to the claims of *every* out-of-state Invokana plaintiff *everywhere* in the world—a result that plainly runs afoul of *Daimler AG v. Bauman*, 134 S. Ct. 746, 760–61 (2014).

Nor can the Non-California Plaintiffs piggyback on the specific jurisdiction that exists over Janssen with respect to the claims of Mr. Dumas. While Plaintiffs argue that their claims are properly joined—as explained, they are not (*see* Defs.' Mem. at 7 (discussing, *inter alia*, *Medtronic* and *Robinson*))—Plaintiffs fail to address the fundamental point that joinder rules *cannot* extend a court's jurisdiction beyond the limits of due process. *Compare* Defs.' Mem. at 7–9, *with* Pls.' Opp'n at 5–7. The Non-California Plaintiffs cannot satisfy their burden of establishing specific jurisdiction by ignoring pivotal arguments. *See, e.g.*, *Silva v. U.S. Bancorp*, 2011 WL 7096576, at *3 (C.D. Cal. Oct. 6, 2011) ("It is well understood . . . that when a plaintiff files an opposition to a motion to dismiss addressing only certain arguments raised by the defendant, a court may treat those arguments that the plaintiff failed to address as conceded." (quoting *Hopkins v. Women's Div., Gen. Bd. of Global Ministries*, 238 F. Supp. 2d 174, 178 (D.D.C. 2002))). Because their piggyback jurisdiction theory has no merit, the Non-California Plaintiffs have failed to establish that Janssen is subject to specific jurisdiction with respect to *their* individual claims. *See, e.g.*, *In re Testosterone Replacement Therapy Prods. Liab. Litig. (Liggins v. Abbvie Inc.)*, 2016 WL 640520, at *4–*6 (N.D. Ill. Feb. 18, 2016) (holding that defendants' Missouri contacts that gave rise

to Missouri plaintiff's claims were "inadequate to confer jurisdiction over defendants" with respect to Illinois plaintiff's claims); *Robinson v. Johnson & Johnson*, 2015 WL 3923292, at *5 (Cal. Super. Ct. June 22, 2015) ("That 67 plaintiffs have banded together . . . in one suit . . . does not change the analysis. . . . By the nature of the product, each plaintiff had a separate surgery by a specific treating physician for a specific set of complaints with a specific medical history. That the products and their disclosure warnings were the same or similar . . . is not enough to make the jurisdictional facts relevant to a California plaintiff applicable to a non-California plaintiff.").

B. The Court Should Dismiss All Plaintiffs' Claims Against McKesson.

Notwithstanding their overblown rhetoric (Pls.' Opp'n at 7), Plaintiffs did *not* clearly allege that McKesson in fact distributed the actual Invokana that they (or their spouses) purportedly ingested. *See* First Am. Compl. ¶ 80. If Plaintiffs had a factual basis for making that claim, they could have alleged it clearly and unequivocally—particularly since they amended their initial Complaint, which contained *no* such allegations, in response to McKesson's argument. *See* Doc. 8–1 (Apr. 5, 2016) at 10–11. Because the First Amended Complaint *still* does not sufficiently allege that McKesson distributed the Invokana allegedly prescribed to and taken by Plaintiffs (or their spouses), the claims against McKesson must be dismissed. *See* Defs.' Mem. at 9–11.

Plaintiffs' reliance on *Bay Summit Community Association v. Shell Oil Co.*, 51 Cal. App. 4th 762 (1996) underscores that Plaintiffs apparently have no factual basis for alleging that McKesson distributed the Invokana that they allegedly ingested. To impose liability against McKesson under *Bay Summit*, Plaintiffs must allege that (1) McKesson received a direct financial benefit from its alleged activities, (2) McKesson's role was integral to the business enterprise such that its conduct was a necessary factor in bringing Invokana to the initial consumer market, and (3) McKesson had control over, or a substantial ability to influence, the manufacturing or distributions process. Pls.' Opp'n at 8–9 (citing *Bay Summit*, 51 Cal. Appl. 4th at 776). But the First Amended Complaint contains *no* such allegations. *See generally* First Am. Compl. Plaintiffs' claims against

McKesson thus fail under *Bay Summit* as well.

C. The Court Should Dismiss Mr. Dumas's Claims Against Janssen.

Each of Mr. Dumas's claims against Janssen is insufficiently pled.

1. The strict liability design defect claim fails.

Mr. Dumas admits that prescription drug manufacturers may *not* be held strictly liable for design defects. *See* Pls.' Opp'n at 9. He argues—without *any* legal support or rationale—that there should be an exception to this rule "when the drug is contraindicated in a population." *Id.* This argument is a nonstarter. The First Amended Complaint does not allege that Invokana was contraindicated in patients like Mr. Dumas. Moreover, to the extent Mr. Dumas argues that it "should have been contraindicated for certain individuals such as Plaintiffs" (*id.*), he seeks to impermissibly second-guess the FDA's judgment in approving Invokana and contraindicating it only in specific populations. *See Horn v. Thoratec Corp.*, 376 F.3d 163, 178 (3d Cir. 2004) ("It is inappropriate for a jury to second-guess FDA's scientific judgment on such a matter within FDA's particular expertise." (internal citations omitted)); *see also* Prescribing Information at 3 (discussing contraindications) (cited in Defs.' Mem. at 12 n.13). Thus, Count 1 fails.

2. The failure-to-warn claim fails.

Mr. Dumas argues that (1) the Prescribing Information is inadequate, (2) Janssen owed a duty to warn him directly through the Medication Guide, and (3) he may base his claim on risks he did not experience. *See* Pls.' Opp'n at 10. Each argument lacks merit.

First, Mr. Dumas does not and cannot deny that the Prescribing Information warned about the very injury that he allegedly experienced—*i.e.*, kidney failure. *Compare* Defs.' Mem. at 12–13, *with* Pls.' Opp'n at 11–12. Nor does he allege any *facts* to explain why or how that warning supposedly was insufficient to apprise his prescribing physician about a risk of kidney failure. *See generally* First Am. Compl. Mr. Dumas cannot satisfy his burden of alleging the grounds of *his* entitlement to relief (*see Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)) by making generic and abstract arguments untethered to the facts underlying *his* claims. *See* Pls.' Opp'n at 10–13. Moreover, Mr.

Dumas's argument—*i.e.*, that the warning concerning kidney failure should have appeared in the Warnings and Precautions, rather than the Adverse Events, section of the Prescribing Information (*see id.* at 11–12)—overlooks the fact that both sections warn about "impairment of renal function." Defs.' Mem. at 12 & n.13. Mr. Dumas cites no case law supporting his position that a plaintiff may pursue a failure-to-warn claim when the defendant warned about the very injury at issue. The *Guidry* court correctly *rejected* that proposition. *See Guidry v. Janssen Pharms., Inc.*, 2016 WL 633673, at *5 & n.9 (E.D. La. Feb. 17, 2016) (finding that plaintiff did not "provide any factual basis for her claim that the defendants failed to adequately warn of acute kidney injury and acute kidney failure" and that "the Prescribing Information of Invokana . . . does contain warnings of renal-related adverse effects"). This Court should do so as well.

Second, Mr. Dumas's Medication Guide argument is legally and factually baseless. Courts across the country have rejected this argument, holding that the learned intermediary doctrine bars *any* claim based on a duty to warn the patient directly. *See, e.g.*, *Small v. Amgen, Inc.*, 134 F. Supp. 3d 1358, 1369 (M.D. Fla. 2015) ("[T]he learned intermediary doctrine is not abrogated by the medication guide regulations."); *Frazier v. Mylan Inc.*, 911 F. Supp. 2d 1285, 1290 (N.D. Ga. 2012) (rejecting claim that Pfizer failed to issue medication guide because learned intermediary doctrine imposes duty to warn only the physician). In addition, the Medication Guide in effect when Mr. Dumas allegedly used Invokana expressly identified "kidney problems" as among "the most important information" that patients should know about Invokana. *See* Prescribing Information at 39; *see also Shah v. Forest Labs., Inc.*, 2015 WL 3396813, at *7 (N.D. Ill. May 26, 2015) (dismissing failure to warn claim where medication guide warned about alleged injury).

Finally, Mr. Dumas has cited *no* case law supporting that he may assert a claim for failure-to-warn about risks he did not experience. As explained, multiple courts have *rejected* that argument. *See Guidry*, 2016 WL 633673, at *4 (dismissing claim premised on failure to warn about risk of diabetic ketoacidosis since plaintiff did not experience

that condition); *Austin v. Bayer Pharms. Corp.*, 2013 WL 5406589, at *7 (S.D. Miss. Sept. 25, 2013) ("Plaintiff failed to state a claim for the failure to warn of side effects which Plaintiff did not suffer."); Defs.' Mem. at 12 n.12 (citing additional authority).

3. The negligence-based claims (Counts 3, 4, and 8) fail.

Mr. Dumas's Opposition confirms that his claims for negligence (Count 3), gross negligence (Count 4), and negligent misrepresentation (Count 8) are insufficiently pled.

a. The negligence claim is not plausible.

Because Mr. Dumas's design defect and failure-to-warn claims fail, so too does his negligence claim. *See supra* Part III.C.1–2. In addition, his failure to include any facts to support his bare recitation of the elements of a negligence claim only underscores that the conclusory allegations in the First Amended Complaint fail under *Twombly-Iqbal*.

b. The gross negligence claim is not plausible.

As this Court recognized in *Wallace v. Busch Entertainment Corp.*, 837 F. Supp. 2d 1093 (S.D. Cal. 2011), "[g]ross negligence is not so much a cause of action as it is a 'limitation on the defense that is provided by a release.'" *Id.* at 1101 (quoting *City of Santa Barbara v. Super. Ct. (Janeway),* 41 Cal. 4th 747, 780 n.58 (2007)). There is no basis to recognize a distinct cause of action for gross negligence here.

c. The negligent misrepresentation claim is not plausible.

Mr. Dumas does not separately address Defendants' arguments with respect to his negligent misrepresentation claim, contending only that this claim mirrors his failure-to-warn claim. *See* Pls.' Opp'n at 15. Because Count 2 fails, Count 8 also fails. *See, e.g.*, *Miller v. Pfizer Inc.*, 2014 WL 2155020, at *5 (N.D. Ala. May 22, 2014) (dismissing negligent misrepresentation claim based on purported failure to warn where complaint provided insufficient factual support to maintain such a claim).

4. The implied warranty claim fails.

Mr. Dumas does not address Defendants' arguments concerning his implied warranty claim. *Compare* Defs.' Mem. at 14–15, *with* Pls.' Opp'n at 15–17. The Court may construe his failure to respond as a concession that his implied warranty claim has

no merit. *Silva*, 2011 WL 7096576, at *3. Thus, the Court should dismiss Count 5.

5. The express warranty claim fails.

Mr. Dumas argues that his express warranty claim is viable because (1) Janssen expressly represented that Invokana was safe and effective, and (2) the Prescribing Information supposedly does not warn about kidney failure and other purported risks. *See* Pls.' Opp'n at 16. As already explained, each argument lacks merit. *See* Defs.' Mem. at 15–17.

First, Mr. Dumas *cannot* base his claim on an alleged warranty that Invokana was safe and effective. In California, plaintiffs "must 'allege the exact terms of the warranty.'" *Bem v. Stryker Corp.*, 2015 WL 6089819, at *2 (N.D. Cal. Oct. 16, 2015) (dismissing claim where plaintiff failed to plead specific language allegedly used to create the express warranty) (quoting *Williams v. Beechnut Nutrition Corp.*, 185 Cal. App. 3d 135, 142 (1986)). And none of the allegations that he cites identifies the "exact terms" of any express warranty. *See* Pls.' Opp'n at 17 (citing First Am. Compl. ¶¶ 56, 76–77, 83, 88, 102, 120, 198–201). Further, any statement that a drug is "safe and effective" cannot create an express warranty. *See, e.g.*, *id.* (dismissing claim premised on allegation that hip replacement device "was a safe and effective option to [plaintiff's] care and treatment"); *Coleman v. Boston Scientific Corp.*, 2011 WL 3813173, at *4 (E.D. Cal. Aug. 29, 2011) (holding that allegations that defendants "advertised their products as safe and effective . . . . are insufficient to support . . . an express warranty claim").

Second, Mr. Dumas cannot premise his warranty claim on an allegation that Defendants failed to warn. An express warranty is created by an "affirmation of fact or promise"—not an *omission*. CAL. COM. CODE § 2313(1)(a); *see also In re Testosterone Replacement Therapy Prods. Liab. Litig.*, 2014 WL 7365872, at *8 (N.D. Ill. Dec. 23, 2014) (explaining that a plaintiff "must plead more than misstatements and omissions to state a claim for breach of express warranty").[1] Mr. Dumas cites no authority to the contrary. *See* Pls.' Opp'n at 15–17.

[1] Further, even if Mr. Dumas could premise his express warranty claim on a failure-to-warn, his claim fails for the same reasons as Count 2. *See also Guidry*, 2016 WL

6. The fraud-based claims (Counts 7–10) fail.

Mr. Dumas's arguments concerning his fraud-based claims lack the same level of detail as the claims themselves. He does *not* dispute that he failed to allege the necessary details concerning any allegedly fraudulent misrepresentation, including its substance and when, by whom, and in what context it supposedly was made. *Compare* Defs.' Mem. at 17–18, *with* Pls.' Opp'n at 18–20. Instead, he simply rehashes his insufficient allegations. He also attempts to justify his improper lumping together of all Defendants in each claim by arguing that "this is not a case of independent actors with independent liability requiring these allegations to be parsed in the Complaint." Pls.' Opp'n at 18. But he cites *no* case law to support that proposition, which directly contradicts the Ninth Circuit's determination that Rule 9(b) "does not allow a complaint to merely lump multiple defendants together but *require[s]* plaintiffs to differentiate their allegations . . . and inform *each defendant separately* of the allegations surrounding his alleged participation in the fraud." *Swartz v. KPMG LLP*, 476 F.3d 756, 764–65 (9th Cir. 2007) (emphasis added).

7. The unjust enrichment claim (Count 12) fails.

Mr. Dumas did not address the argument concerning his unjust enrichment claim. *Compare* Defs.' Mem. at 18, *with generally* Pls.' Opp'n. Thus, Count 12 fails.

8. The Section 17200 claim (Count 13) fails.

Mr. Dumas also did not address the argument that his Section 17200 claim fails to allege acts or practices that are unlawful or unfair. *Compare* Defs.' Mem. at 18–19, *with* Pls.' Opp'n at 21. Instead, he contends that the claim sufficiently plead acts or practices that were fraudulent. *See* Pls.' Opp'n at 21. As explained, Mr. Dumas did *not* sufficiently allege fraud as required by Rule 9(b). *See* Defs.' Mem. at 19; *supra* Part II.C.6. Because his allegations fail to include "the time, place, and specific content of the false representations as well as the parties to the misrepresentations," the Court should dismiss Count 13. *In re Sony Grand Wega KDF-E A10/A20 Series Rear Projection*

633673, at *5 (dismissing express warranty claim that "largely reasserts the grounds for her failure-to-warn claim").

HDTV Tele. Litig., 758 F. Supp. 2d 1077, 1092 (S.D. Cal. 2010); *see also Wright v. Gen. Mills, Inc.*, 2009 WL 3247148, at *6 (S.D. Cal. Sept. 30, 2009) (dismissing section 17200 claim where plaintiff did not plead claim with particularity under Rule 9(b)) (Lorenz, J.).

9. The Section 17500 claim (Count 14) fails.

Like his Section 17200 claim, Mr. Dumas's Section 17500 claim is pled with *no* particularity. Instead, it merely alleges that Defendants publicized "statements, representations and promotional schemes" that were "deceptive, false, incomplete, misleading and untrue." Compl. ¶ 276. While Mr. Dumas argues that the First Amended Complaint alleges actual reliance by his physician, the allegations to which he cites—which are *not* specific to Mr. Dumas—merely allege reliance on vague and conclusory statements that Invokana was "safe and effective" and unidentified "advertising" and "misrepresentations and omissions." Pls.' Opp'n at 21 (citing First Am. Compl. ¶¶ 118–120). These allegations are equally lacking in the requisite particularity.

D. <u>Plaintiffs' Design Defect-Based Claims Are Preempted By Federal Law.</u>

Plaintiffs argue that the preemption principles in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), and *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013), apply only to generic, not branded, drugs. But that argument is demonstrably wrong.

As Defendants explained, the Supreme Court and other courts have confirmed that *Mensing* and *Bartlett* state a general principle of conflict preemption that is *not* limited to the generic drug context. *See* Defs.' Mem. at 22 & n.20 (discussing *Wos*, *Sikkelee*, *In re Celexa*, and *Horseman's*). Consistent with these authorities, the Sixth Circuit specifically *rejected* Plaintiffs' argument, finding that a design defect claim involving a *branded* prescription drug *was* preempted under *Mensing* and *Bartlett*. *See Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 298 (6th Cir. 2015) (holding that plaintiff's post-FDA approval design defect claim "is clearly preempted by federal law" because "defendants could not have altered the dosage of estrogen" in brand-name Ortho Evra without FDA's prior approval). Many other courts have reached the exact same conclusion. *See* Defs.' Mem. at 23–24 & nn.21, 22 (discussing *Barcal*, *Batoh*,

Rheinfrank, *Shah*, *Yates*, *Booker*, *Amos*, and *Thompson*).[2]

In addition, Plaintiffs cannot avoid preemption by arguing that Defendants should have redesigned Invokana *before* the FDA approved it. *See* Pls.' Opp'n at 24–26. The Sixth Circuit *rejected* a "pre-approval" design defect claim in *Yates* as "too attenuated" because it required the court to assume that (1) the FDA would have approved an alternate design for the branded prescription drug, (2) the plaintiff would have elected to use the alternatively-designed product, and (3) the alternate design would not have caused the plaintiff's injury. *See Yates*, 808 F.3d at 299. Further, the court confirmed that "Defendants could not have complied with whatever pre-approval duty might exist without ultimately seeking the FDA's prior approval to marketing [the drug]." *Id.* (citing *Mensing*, 131 S. Ct. at 2581). The same is true here.[3]

The court in *Yates* rejected the plaintiff's pre-approval design defect claim for another, independent reason. It found that by seeking to impose a pre-approval duty to design Ortho Evra differently, the plaintiff "essentially argue[d] that defendants never should have sold the FDA-approved formulation of [the drug] in the first place." *Id.* at 300. Relying on *Bartlett*, the court categorically *rejected* this "never-start selling rationale." *Id.* (quoting *Bartlett*, 133 S. Ct. at 2470, 2477 (rejecting argument that manufacturer should have pulled drug from market in order to comply with both state and

[2] Defendants are not arguing that *all* design defect claims involving brand-name drugs are preempted, as Plaintiffs argue. *See* Pls.' Opp'n at 25–26. Instead, Defendants merely contend that the claims at issue here—which Plaintiffs do *not* dispute are premised on a design change that is subject to the "major changes" regulation and that requires prior FDA approval—are preempted. Further, an order granting this motion will *not* "render drug companies completely immune from suit once they obtain FDA approval." *Id.* at 25. While plaintiffs cannot assert design defect claims like the claims at issue here, they still may assert failure-to-warn claims in appropriate cases.

[3] Plaintiffs can derive no support from *Wimbush v. Wyeth*, 619 F.3d 632 (6th Cir. 2010). *See* Pls.' Opp'n at 26. Indeed, the court in *Yates* rejected application of *Wimbush* because the plaintiff failed to explain "precisely what a pre-approval claim would look like." *Yates*, 808 F.3d at 300. So too here. Plaintiffs have not articulated what a pre-approval claim would look like and how such a claim would be any less attenuated than the claim rejected in *Yates*. Moreover, contrary to Plaintiffs' suggestion (*see* Pls.' Opp'n at 25), it makes no difference that Plaintiffs began using Invokana when it was newly on the market. Regardless of how long Invokana had been on the market, Defendants would have had to seek and obtain the FDA's approval before marketing an alternatively designed product.

federal law and reasoning that this "stop-selling" rational is "incompatible with . . . preemption jurisprudence," which "presume[s] that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability")). The court's reasoning makes good sense given the FDA's exclusive authority to approve new drugs in the United States. *See* 21 U.S.C. § 355(a)–(d). Because federal law "effectively reserves the launch of new drugs to the expertise of the FDA," *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 41 (1st Cir. 2015), the Court should not permit Plaintiffs to pursue claims that effectively would overrule the FDA's determination that Invokana had an appropriate risk-benefit profile when the agency approved the drug.

Finally, multiple courts have resolved the preemption issue at the pleading stage. *See* Defs.' Mem. at 20 (citing *Mensing*, *Barcal*, *Amos*, and *Thompson*). And contrary to Plaintiffs' argument (*see* Pls.' Opp'n at 27), no amount of discovery will aid in resolving the purely legal question before the Court. Because Plaintiffs' design defect-based claims are preempted, the Court can and should dismiss them now with prejudice.[4]

E. Plaintiffs' Claims Against McKesson Are Preempted By Federal Law.

Plaintiffs concede that McKesson "cannot independently change the label for Invokana." Pls.' Opp'n at 28. And they do not and cannot dispute that McKesson could *not* independently alter the drug's design. *See id.* Nor do they dispute that, as a non-NDA-holder, McKesson cannot be held liable for claims premised on a failure to change

[4] Plaintiffs' cited cases do *not* demand a different result. *Estate of Cassel v. Alza Corp.*, 2014 WL 856023, at *5 (W.D. Wis. Mar. 5, 2014), is contrary to *Mensing* and *Bartlett*, in which the Supreme Court rejected arguments that a manufacturer should take steps to bring a safer product to market by "asking for the FDA's help" (*Mensing*, 131 S. Ct. at 2581) or should "stop selling" a regulated product (*Bartlett*, 133 S. Ct. at 2493). *Sullivan v. Aventis, Inc.*, 2015 WL 4879112 (S.D.N.Y. Aug. 13, 2015) and *Acree v. Watson Pharmaceuticals, Inc.*, 2012 WL 5306296 (N.D. Ill. Oct. 26, 2012) are unavailing for the same reasons as *Cassel*. *In re Tylenol (Acetaminophen) Marketing, Sales Practices & Products Liability Litigation*, 2015 WL 7075949 (E.D. Pa. Nov. 13, 2015) and *Brown v. Johnson & Johnson*, 64 F. Supp. 3d 717 (E.D. Pa. 2014) fail to properly apply *Mensing* and *Bartlett*, instead using *Wyeth*'s "clear evidence" test without considering whether the FDA would have to first approve an alternatively designed drug. And *Dopson-Troutt v. Novartis Pharmaceutical Corp.*, 975 F. Supp. 2d 1209 (M.D. Fla. 2013), turned on the manufacturer's ability to change the drug's label, not its design, without the FDA's "permission and assistance."

Invokana's design or warnings. *See id.* Instead, they argue merely that McKesson "provide[s] information to physicians beyond what is contained in the label" and therefore may be held liable for claims that do not depend on McKesson itself changing the label. *Id.* But Plaintiffs neglect to identify which claims those are. And there are *no* allegations in the First Amended Complaint sufficiently identifying what "information" beyond the label McKesson supposedly provided to any of Plaintiffs' physicians. For all these reasons, the Court should dismiss Plaintiffs' claims against McKesson as preempted. *See* Defs.' Mem. at 24–25.

F. The Court Should Deny Plaintiffs' Alternative Requests To Amend The Complaint And For Jurisdictional Discovery.

The Court should deny Plaintiffs' request for leave to amend. *See* Pls.' Opp'n at 29. If Plaintiffs wish to amend their pleading for a second time, they should file an appropriate motion with the Court. *See Gardner v. CafePress, Inc.*, 2014 WL 7183704, at *4 (S.D. Cal. Dec. 16, 2014) ("As Plaintiff has sought leave to amend in an opposition rather than in a motion, the Court declines to consider the issue of leave to amend.").

Likewise, the Court should reject Plaintiffs' request for jurisdictional discovery (*see* Pls.' Opp'n at 29–30) given the Non-California Plaintiffs' failure sufficiently to allege that their claims arise out of or relate to any contacts that Janssen purposely directed at California. In addition, Plaintiffs have not made a proper request for jurisdictional discovery. *See, e.g.*, *Mother Doe I v. Al Maktoum*, 632 F. Supp. 2d 1130, 1146 (S.D. Fla. July 30, 2007) (explaining that request for jurisdictional discovery in opposition memorandum is "not a substitute for the issuance of discovery requests").[5]

III. CONCLUSION

For the reasons stated, the Court should grant Defendants' Motion in its entirety.

[5] If the Court were to allow any such discovery, it must be narrowly tailored so it is "proportional to the needs of the case," FED. R. CIV. P. 26(b)(1), and Plaintiffs should pay for it. *See* FED. R. CIV. P. 26(c)(1)(B) (permitting "allocation of expenses" to requesting party to protect against "undue burden or expense"). Shifting the cost of discovery to Plaintiffs is appropriate here, because Plaintiffs have failed to identify—let alone with the requisite specificity—what discovery they supposedly need or how they expect to establish facts to support jurisdiction. *See, e.g.*, *Ashmore v. Allied Energy, Inc.*, 2016 WL 301169, at *2 (D.S.C. Jan. 25, 2016) (discussing factors governing cost-shifting).

DATED: June 6, 2016

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